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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,736	04/16/2004	James R. Matson	3154/113	1355
2101 7590 07/30/2008 BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618				
EXAMINER DEAK, LESLIE R				
ART UNIT 3761		PAPER NUMBER		
MAIL DATE 07/30/2008		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/826,736

Applicant(s)

MATSON ET AL.

Examiner

LESLIE R. DEAK

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-24 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 16-24 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/5508)
Paper No(s)/Mail Date 5/29/08
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 29 May 2008 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 787 500 A1 to Wratten et al in view of US 5,571,418 to Lee et al.

In the specification and figures, Wratten discloses a hemofiltration device substantially as claimed by Applicant. With regard to claims 16 and 18, comprising a first conduit 1 that directs a blood stream from a source 4 to a hemofilter 5, a second conduit 9 that directs the filtered blood stream back to the source 4, a third conduit 8 that directs the ultrafiltrate stream to an adsorption device 11/12 that contacts the ultrafiltrate stream with an adsorptive material to remove cytokines, which are

inflammatory mediators, and a fourth conduit (unlabeled) that directs the postadsorptive ultrafiltrate back to the source (see FIG 1 and accompanying text).

Wratten fails to disclose that the conduits direct fluid to and from a mammal. Applicant's recitation that the conduits are "adapted to" perform a particular function are not a positive structural recitation but require only the ability to function as claimed. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate from a prior art apparatus satisfying the claimed structural limitations. Applicant has not set forth any structural limitations that accomplish the claimed function or differentiate from the conduits disclosed by Wratten. Furthermore, Wratten but discloses that fluid may be taken and returned to the patient using known means (see Wratten, p4, lines 10-20). Accordingly, the Wratten disclosure reasonably suggests to one of ordinary skill in the art that the disclosed conduits are capable of directing fluid flow between the locations claimed by applicant, satisfying the limitations of the claims.

Wratten does not specifically disclose the porosity of hemofilter 5, but does disclose that it has a small pore size. Lee discloses hemofiltration of toxic mediator-related disease comprising the steps of withdrawing blood from a mammal, filtering the blood, and returning the filtered blood to the patient (see Lee column 4, lines 32-39). The filter used by Lee may have a molecular weight exclusion limit of 100,000 to 150,000 Daltons, which is "greater then or equal to 69,000 Daltons" as claimed by applicant. Lee discloses that the larger Dalton filter (which is capable of allowing albumin to pass into the ultrafiltration stream) improves results over the prior art smaller pore filters (see column 2, lines 5-15, column 3, lines 15-31). Therefore, it would have

been obvious to one having ordinary skill in the art at the time of invention to substitute the large pore filter disclosed by Lee for the hemofilter disclosed by Wratten in order to increase treatment effects, as taught by Lee.

With regard to claim 22, Lee discloses that the hemofilter may be made of polysulfone or polyamide (see column 1, lines 59-61).

With regard to claims 23 and 24, Wratten discloses that the adsorbent material may comprise activated carbon or polystyrene resins (see page 2, lines 40-66).

4. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 787 500 A1 to Wratten et al in view of US 5,571,418 to Lee et al, further in view of US 5,846,419 to Nederlof.

In the specification and figures, Wratten and Lee disclose the apparatus substantially as claimed by applicant (see rejection above).

With regard to claim 17, the cited prior art fails to disclose the merging of the first and fourth conduits to provide a combined post-treatment stream of fluid.

Nederlof discloses an extracorporeal blood treatment apparatus comprising a first conduit or patient blood supply line 82 that directs blood from a mammal to a blood filtration device 12, a second conduit 84/85 that directs fluid from the filter 12 back to the mammal, a third conduit 70 that directs ultrafiltrate from the filter to a second treatment apparatus 60, and a fourth conduit 72/85 that receives fluid from a second treatment apparatus and returns the treated fluid to the mammal. The second conduit 84 and the fourth conduit 72 merge at reservoir 78 to combine the post-treatment streams into a single stream supplied by conduit 85 for return to the mammal.

With regard to claims 19-21, the cited prior art fails to disclose a fifth conduit for splitting ultrafiltrate into a waste stream and a return stream, wherein the divider is a three-way joint. Nederlof discloses that discharge line 24 comprises a joint with line 52 and line 25 where ultrafiltrate is divided with some going to drain or waste container 90 (see FIG 1).

All the component parts of the instantly claimed invention are known in the prior art. The only difference is the combination of the known elements into a single apparatus by merging the return fluid lines disclosed by Wratten. This, it would have been obvious to one having ordinary skill in the art to merge the second and fourth conduits disclosed by Wratten to form a single, combined fluid stream as disclosed by Nederlof, as well as use a fifth conduit and divider to divert some ultrafiltrate to a waste container, as disclosed by Nederlof, since the operation of the Wratten device is in no way dependent on the combination or diversion of the fluid stream for patient return, and the combined fluid stream is easily used in combination with a two-fluid return apparatus to achieve the predictable results of providing a combined fluid stream to the patient and discarding waste fluid.

Response to Amendment/Arguments

5. Applicant's amendment and arguments filed 29 May 2008 have been entered and considered.
6. Applicant's arguments drawn to the incompatibility of the Wratten and Lee references has been fully considered but is unpersuasive. Applicant specifically argues that since Wratten and Lee are used for two different elimination procedures, one of

ordinary skill in the art would not look to the other reference to teach the instantly claimed invention. It is the position of the Examiner that the extracorporeal circuit disclosed by Wratten is capable of being modified by substitution of the filter disclosed by Lee in order to accomplish a different filtering operation, which Lee specifically discloses is an improvement over the prior art. However, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Accordingly, it is the position of the Examiner that taken together as a whole, the references teach the extracorporeal tubing arrangement disclosed by Wratten and a filter with a pore size disclosed by Lee, which can be combined, with no change in the functions of the respective elements, to arrive at an extracorporeal circuit with a filter comprising a small pore size.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner
Art Unit 3761
28 July 2008